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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/316,624	05/21/99	HIRSCHMAN S	4493-19CIP

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EXAMINER	
ZEMAN, M	
ART UNIT	**PAPER NUMBER**
1631	8

DATE MAILED: 05/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/316,624	Applicant(s) HIRSCHMAN, SHALOM Z.	
	Examiner Mary Zeman	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

DETAILED ACTION

Continued Prosecution Application

The request filed on 3/20/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/316,624 is acceptable and a CPA has been established. An action on the CPA follows.

No further amendments or arguments have been filed as of the date of this action.

Claims 1-4 are pending in this application.

Applicant's arguments filed 7/3/00 have been fully considered but they are not persuasive. All non-reiterated rejections have been withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections maintained

Claims 1-4 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the previous office action.

The metes and bounds of the phrase "effective symptom ameliorating amount" in claims 1 and 4 are unclear. Applicant argues that one of skill in the art can readily determine the appropriate amounts to be given, these arguments are not persuasive, in that no standard levels of activity are set forth for the Product R preparations, nor does the specification indicate how activities of the Product R are to be determined. While the claims set forth a volume of solution to be administered, there is no correlation between the volume to be administered, and the active units present in that volume of the formulation, such that one of ordinary skill in the art would be apprised of the scope of the invention. The specification provides two methods for making the Product R, but it is unclear that the two resulting products have the same levels of activity. There is no titration of the active Product R formulations such that one of skill in the art would be able to estimate proper dosages to be given. This is true especially in light of the wide range of volumes to be administered. 2.5 microliters (2.5×10^{-6} liters) is a miniscule amount of liquid, especially in comparison to 1 milliliter (1×10^{-3} liters) of liquid.

Claims 1-4 remain rejected under 35 U.S.C. 102(e) as being anticipated by Kochel (US Patent 5,849,196) for the reasons set forth in the previous office action.

The claims are drawn to methods of treating symptoms of rheumatoid arthritis by the administration of Product R. The specification describes Product R as a filtered form of a product "Reticulose", made from casein, beef peptone, RNA, serum, Sodium Hydroxide and distilled water. The mixture is passed through at least a 0.45 micron filter, then a 0.2 micron filter. No chemical, or biochemical analysis of the final composition is set forth in the specification, or claims.

Applicant argues that the product of Kochel is completely unlike that of the present invention, and provides the specification of a copending application setting forth a comparison therewith. However, Applicant is arguing limitations not present in the pending claims. The pending claims do not recite particular physical properties of the Product R which are different from that of the Product R of Kochel, nor do the claims recite the particular methods used to isolate or purify the Product R of the claims that results in the differing composition. As such, the pending claims still include the compositions of Kochel within their scope.

Kochel (US Patent 5,849,196, filed Oct. 7, 1996) discloses a composition which is derived from the filtration of "Reticulose", which can be used to treat autoimmune disorders, such as rheumatoid arthritis. Kochel discloses the preparation of the composition at columns 5 and 6, and discloses the final proportions of the components. Kochel discloses that the compositions having the lower molecular weight peptides (<8-15 Kd) are useful in the treatment of autoimmune diseases at column 3 lines 1-11. The claims recite Product R, which appears to be made by specific processes in the specification. The MPEP discusses product-by -process claims in chapter 2100: "Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by -process claim is the same as, or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process." See MPEP 2113.

Kochel sets forth products derived from the known product "Reticulose" and methods of using that product, as claimed. The methods Kochel used to produce the composition, as well as the methods of treating rheumatoid arthritis, are very similar to those of the claimed invention.

Whether the products resulting from the process are the same, is not clear, and the Office does not have the facilities to perform such comparative analyses. In a discussion of product-by-process claims, the court has said: "[W]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 59 CCPA 1036, 1041, 459 F.2d 531, 535, 173 USPQ 685, 688 (1972). The court further addressed the issue of product-by process claims in In re Best: "the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on 'inherency' under 35 USC 102, on 'prima facie obviousness' under 35 USC 103, jointly or alternatively, the burden of proof is the same [footnote omitted]." In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977).

Conclusion

No claim is allowed.

This is a CPA of applicant's earlier Application No. 09/316,624. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however,

event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner□s supervisor, Michael Woodward, can be reached at (703) 308 4028.

The fax number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center receptionist whose telephone number is (703) 308-0196.

mkz
May 7, 2001

Mary K Zeman
MARY K. ZEMAN
PATENT EXAMINER
AU 1631